

REMARKS

Claims 50-69 and 73-79 are pending. Claims 50-64 have been allowed. Claims 70-72 have been canceled without prejudice. Claim 65 has been amended to recite that “acquiring a first arrhythmia signal within a sinus rhythm. Support for amended claim 65 can be found at, for example, page 18, lines 1-2. Claim 66 has been amended to independent claim format.

Rejection of Claims 65-69 Under 35 U.S.C. § 103(a)

Claims 65-69 have been rejected under 35 U.S.C. § 103(a) as obvious over Mlynash et al., U.S. Patent No. 6,615,075 (“Mlynash”). According to the Examiner, Mlynash discloses aligning an arrhythmia signal and a QRST template, and calculating a cross-correlation. The Examiner contends that it would have been obvious to one of ordinary skill in the art to create templates for an arrhythmia signal because Mlynash discloses means that may be used to adjust “fiducial points and windows as a signal sliding means, signal stretching or compressing means, variable signal adjusting means, or the like” (Office Action mailed July 12, 2004, page 4).

Claim 65 has been amended to specify that the patient has a sinus rhythm. According to Mlynash, only in cases where chronic atrial fibrillation is present (e.g., there is no sinus rhythm), can a non-sinus rhythm or non-atrial pacing signal be used to create a template (Mlynash, col. 4, lines 37-40). According to Mlynash, in all other cases, “a clear distinction is made between the electrical heart signals obtained during an arrhythmia, called arrhythmia signals, and the electrical signals obtained during sinus rhythm or atrial pacing, called template signals that are used to create the QRST template” (Mlynash, col. 4, lines 28-33). Thus, amended claim 65 distinguishes Mlynash. Further, Mlynash is directed to identifying an arrhythmia in a patient, not multiple arrhythmias. In the case of chronic atrial fibrillation according to Mlynash, the chronic atrial fibrillation is simply the patient’s baseline electrocardiac signal and does not require identification. Thus, even in the case of chronic atrial fibrillation according to Mlynash, the method is directed to the identification of a single arrhythmia.

Claims 66-69 are directed to methods for identifying multiple distinct arrhythmias wherein at least two arrhythmia signals are defined as templates. Mlynash does not disclose or suggest a set of such templates. Further claims 67-69 are directed to methods, which include a pace mapping catheter in or adjacent the heart. Mlynash is directed to noninvasive methods (see e.g., Mlynash abstract) and does not disclose or suggest such invasive methods.

As discussed above, Mlynash is not directed to the identification of multiple distinct arrhythmia signals. The distinction between identification of multiple distinct arrhythmia signals and the mere identification of one arrhythmia as in Mlynash is substantial as it has diagnostic and clinical implications. “For example, two close in space, but separate and distinct, ectopic foci can emit arrhythmia signals that are morphologically similar” (present specification, page 28, lines 19-20). A clinician must be able to identify whether single or multiple distinct arrhythmias are present for subsequent localization of the ectopic foci and treatment. For example, a clinician who is unable to distinguish two morphologically similar arrhythmias would ablate one ectopic focus in the false belief that only one arrhythmia and, thus, only one ectopic focus is present. This would result in treatment of only one of two arrhythmias.

Further, Mlynash does not disclose or suggest a method for *identifying* multiple distinct arrhythmias because requires at least two electrical heart signals to construct a template:

In an exemplary embodiment, about a hundred cardiac cycles of sixty-two channel ECG data are acquired during sinus rhythm or atrial overdrive pacing for use as template signal. Typically, more than ten cycles are used, often more than fifty for the construction of the QRST template. Fewer cycles may be used if the spatial and temporal variations of the QRST complexes are relatively low. In general, at least two cardiac cycles of template signals can be used.

Mlynash, col. 9, lines 3-11. *See also* col. 2, lines 58-61 and claim 1.

The construction of a template from at least two electric heart signals corresponding to a particular arrhythmia from a series of electrocardiac signals, which include multiple, distinct arrhythmias presupposes that each arrhythmia can be distinguished. The method of Mlynash requires, in order to construct the template, that the multiple, distinct arrhythmias are already identifiable. Thus, the

method of Mlynash can not be used to identify multiple distinct arrhythmias because a template according to Mlynash can not be constructed until *after* the multiple arrhythmias have been identified.

Accordingly, the rejection of claims 65-69 under 35 U.S.C. § 103(a) should be withdrawn.

Rejection of Claims 70-72 Under 35 U.S.C. § 103(a)

Claims 70-72 have been rejected under 35 U.S.C. § 103(a) as obvious over Mlynash. Claims 70-72 will be pursued in co-pending Application Serial No. 10/005,470.

Rejection of Claim 73 Under 35 U.S.C. § 103(a)

Claim 73 has been rejected under 35 U.S.C. § 103(a) as obvious over Mlynash. Claim 73 depends from claim 50, which has been allowed. Thus, claim 73 should be allowed and this rejection should be withdrawn.

The Provisional Rejection Under 35 U.S.C. § 101 For Statutory Double Patenting

Claims 77-79 have been rejected under 35 U.S.C. § 101 for statutory-type double patenting in view of claims 51-53 of Application Serial No. 10/005,470. Applicant will cancel claims 51-53 of Application Serial No. 10/005,470. Upon such cancellation, this rejection will be obviated.

The Provisional Rejection For Obviousness-type Double Patenting

Claims 74-76 have been provisionally rejected for obviousness-type double patenting over claims 10, 15, 16, 25, 56 and 57 of Application Serial No. 10/005,470. Upon the identification of patentable subject matter, Applicant will file a terminal disclaimer to obviate this rejection.

Conclusion

No new matter has been added. All of the pending claims in this application are believed to be in condition for allowance. Entry and consideration of these amendments and remarks are therefore respectfully requested.

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Respectfully submitted,

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